REMARKS

Claims 1-2, 4-18, 20-23, 25, 27-37, 39, and 41 are pending and stand rejected. New claims 42-44 have been added. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

Amendments to the Claims

New claims 42, 43, and 44 are added. These new claims recite that the at least one channel is on the surface of the cell growth conduit flap. Support for these new claims can be found throughout the specification, for example at paragraph 0034 of the published application. No new matter is added.

Rejections Pursuant to 35 U.S.C. §103

Malaviya

The Examiner rejects claims 1, 2, 4-18, and 30-33 pursuant to 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Publication No. 2003/0036797 of Malaviya et al. ("Malaviya"). Applicants respectfully disagree.

Claim 1 recites a biocompatible meniscal repair device that includes a biocompatible tissue repair scaffold and a cell growth conduit flap attached to the tissue repair scaffold. The cell growth conduit flap contacts a tibial surface, extends to the synovium, and comprises at least one channel configured to communicate biological materials to a tissue defect in the meniscus. Claim 1 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Applicants submit that claim 1 distinguishes over and is not obvious in light of Malaviya and represents allowable subject matter.

Malaviya fails to teach or suggest, among other things, a cell growth conduit flap comprising at least one channel configured to communicate biological materials to a tissue defect in the meniscus. Indeed, there is no teaching or suggestion in Malaviya that the tabs, or any other portions of Malaviya's device, include at least one channel configured to communicate biological materials to a tissue defect in the meniscus.

In response to Applicants previous arguments, the Examiner now states that she "considers the pores in the material of Malaviya to be channels that communicate biological materials to the defect as discussed in paragraph 148." Office Action at page 2. However, there is no disclosure in Malaviya to support the Examiner's contention. Malaviya merely discloses a "toughened" implant material that "must be porous enough to permit remodeling." Malaviya at paragraph 0013. There is no teaching or suggestion of any pores in Malaviya's material that can communicate biological materials to a defect. Moreover, there is no teaching or suggestion in Malaviya that there are any such pores in the tabs that facilitate attachment of the device to the surrounding tissue.

The Examiner asserts that "[p]aragraph 148 of Malaviya further discloses that during a recovery period after surgery body fluids such as blood and synovial fluids as well as cells infuse into the implant and begin the remodeling process." Office Action at page 2. However, the disclosure by Malaviya that "body fluids such as blood and synovial fluids infuse into the implant" during a period "without substantial load bearing on the knee" does not teach or suggest that these fluids pass through any portion of Malaviya's device that could be considered a cell growth conduit flap. Indeed, based on the teachings of Malaviya it is not clear whether body fluids can even pass through the toughened outer covers of the implant, much less that there are any channels in these layers that communicate biological materials. To the contrary, Malaviya discloses that when "the knee is sufficiently immobilized for a period of time subsequent to implantation to keep upper cover 161 and lower cover 163 apart, blood and synovial fluid will infiltrate open space 165." Malaviya at paragraph 0153.

In contrast, Applicants' invention provides a cell growth conduit flap with material properties and a structure, i.e. at least one channel, that communicate biological materials to a tissue defect in the meniscus. *See, e.g.*, published application at paragraph 0034. Malaviya teaches that fluids simply move through open space between layers of the device and thus fails to teach a cell growth conduit flap that communicates biological materials.

Moreover, Malaviya also fails to teach or suggest a cell growth conduit flap that contacts a tibial surface and extends to the synovium. The Examiner continues to argue that Malaviya's mensical repair device "is entirely capable of being placed so that it extends to the synovium." Office Action at page 3. The Examiner is incorrect. According to the

teachings of Malaviya, the covers 232, 234, which the Examiner argues form the claimed cell growth conduit flap, cannot extend to the synovium. Malaviya teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to extend to the synovium. Therefore, according to the teachings of Malaviya, the cell growth conduit flap would not be capable of extending to the synovium.

Moreover, even if the device could be positioned such that the covers 232, 234 extended to the synovium, in such a position the device would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device," as taught by Malaviya. *See* Malaviya at Par. 0018. The Examiner now argues that "if the device of Malaviya were extended to the synovium, it could still be in contact with the side portions of the surrounding tissue of the remaining meniscus such that it does not go against the teachings of Malaviya." The Examiner is incorrect. As previously discussed, Malaviya teaches that the outer portion of the meniscus is retained. In particular, Malaviya specifically teaches that the device is positioned "against the rim 18 left by the surgeon." Malaviya at paragraph 0140. The "surrounding tissue" that Malaviya teaches would be in contact with the device is not merely the "side portions of the surrounding tissue," as alleged by the Examiner. Instead, the "surrounding tissue" must include the rim 18, i.e., the retained radially outer portion of the original meniscus. Therefore, positioning the device of Malaviya such that the covers extended to the synovium would run contrary to the teachings of Malaviya. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Accordingly, independent claim 1 distinguishes over Malaviya and represents allowable subject matter. Claims 2, 4-18, and 30-33 likewise distinguish over Malaviya by virtue of their dependence on claim 1.

Malaviya in view of Vallee

The Examiner rejects claims 21, 25, and 27 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of US Patent No. 4,952,404 of Vallee at al. ("Vallee"). Applicants respectfully disagree.

Claim 21 recites a method of surgically repairing meniscal defects that includes positioning a tissue repair scaffold in contact with a defect in a meniscus while positioning a cell growth conduit flap in contact with a tibial surface and the synovium. The Examiner admits that "Malaviya does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium." The Examiner thus relies on Vallee to remedy the deficiencies of Malaviya. In this regard, the Examiner asserts that Vallee "teaches that it is known that meniscal tears may be healed if they communicate with the synovial membrane." The Examiner then argues that it would have been obvious to one of ordinary skill in the art at the time of the invention to "modify the placement of Malaviya such that the covers contact the more vascularized synovium in order to promote healing of the meniscus as taught by Vallee."

At the outset, Vallee merely discloses that "meniscus can be healed by connective tissue provided that the tear communicates with the synovial membrane laterally." Vallee at col. 1, lines 17-19. There is no teaching or suggestion in Vallee regarding the placement of an implant. Moreover, the covers 232, 234 of Malaviya, which the Examiner argues form the claimed cell growth conduit flap, cannot be positioned in contact with a tibial surface and the synovium without disregarding the express teachings of Malaviya. As discussed in more detail above, Malaviya teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to contact the synovium. Moreover, even if the device could be positioned such that the covers 232, 234 contact the synovium, in such a position the device would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device," as taught by Malaviya. *See* Malaviya at paragraph 0018. Therefore, according to the teachings of Malaviya, the cell growth conduit flap would not be capable of extending to the synovium. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If

the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Examiner therefore fails to present a prima facie case of obviousness with respect to claim 21.

Furthermore, claim 21 also recites that the cell growth conduit flap includes at least one channel configured to allow cells and nutrients to travel through the cell growth conduit flap to the defect in the meniscus. As discussed above, there is no teaching or suggestion in Malaviya that the tabs, or any other portions of Malaviya's device, include at least one channel configured to communicate biological materials to a tissue defect in the meniscus. Accordingly, claim 21, as well as claims 22-23 and 39, which depend therefrom, distinguish over Malaviya in view of Vallee and represent allowable subject matter.

Claim 25 recites a method of surgically repairing meniscal defects that includes positioning a cell growth conduit flap in contact with a tissue defect in a meniscus and in contact with a tibial surface and the synovium. Claim 25 also recites that the cell growth conduit flap includes at least one channel effective to allow cells and nutrients to travel through the cell growth conduit flap to the defect in the meniscus. Applicants' arguments with respect to claim 21, above, apply with equal force to claim 25. Accordingly, claim 25, as well as claims 27-29 and 41, which depend therefrom, distinguish over Malaviya in view of Vallee and represent allowable subject matter.

Malaviya in view of Vallee and Li

The Examiner rejects claims 22, 23, 28, and 29 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of Vallee and further in view of US Patent No. 4,790,819 of Li et al. ("Li"). Applicants respectfully disagree.

At the outset, Li fails to remedy the deficiencies of Malaviya in view of Vallee with respect to claims 21 and 25 from which claims 22-23 and claims 28-29 depend. Li does not remedy the deficiencies of Malaviya in view of Vallee with respect to the features recited in claim 21 and 25. *See* Li at col. 1, lines 27-31.

Li is directed to a method of depositing a fibrin clot material into a wound site. Li at Abstract. There is no teaching or suggestion in Li regarding the placement of an implant, e.g., as required by claims 21 and 25. Li thus fails to remedy the deficiencies of Malaviya and Vallee. Claims 21 and 25 therefore distinguish over Malaviya, Vallee, and Li. Claims 22-23 and 28-29 thus distinguish over the combination of these references at least because they depend from claims 21 or 25.

Dependent claims 22-23 and 28-29 also distinguish over Malaviya, Vallee, and Li for other reasons. Claims 22 and 28 recite that the methods of claims 21 and 25 include the step of rasping the meniscus before positioning the cell growth conduit flap. Claims 23 and 29 recite that the methods of claims 21 and 25 include the step of rasping the synovium before positioning the cell growth conduit flap. The Examiner admits that Malaviya does not disclose the step of rasping the meniscus or synovium before positioning the cell growth conduit flap. Office Action at page 8. Like Malaviya, Vallee also fails to disclose any step of rasping the meniscus or synovium. Vallee merely discloses application of an angiogenic factor to promote healing of the meniscus. *See, e.g.,* Vallee at col. 2, lines 60-64. Vallee thus fails to remedy the deficiencies of Malaviya.

Li fails to remedy the deficiencies of Malaviya and Vallee with respect to the claimed methods of rasping the meniscus or synovium before positioning the cell growth conduit flap of a scaffold in contact with a defect in a meniscus and the synovium. Li discloses "a delivery device for depositing an exogenous fibrin clot into a wound site during an arthroscopic surgical operation." Li at Abstract. Although Li discloses "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium to increase blood supply to the meniscal tear" (Li at Col. 1, lines 27-31), Li does not teach or suggest depositing the fibrin clot material in contact with the synovium. Li merely discloses injecting "a quantity of fibrin clot material into the meniscal tear within the wound site." (Li at Col. 6, lines 63-65). In addition, Li does not disclose using any rasping step in combination with depositing the fibrin clot material. Indeed, Li's invention represents an improvement to methods that require rasping the synovium to create a fibrin clot.

Li thus fails to remedy the deficiencies of Malaviya in view of Vallee because Li fails to teach or suggest that the fibrin clot material is placed in contact with the synovium or a cell

growth conduit flap including at least one channel. Claims 22, 23, 28, and 29 therefore distinguish over Malaviya in view of Vallee and Li and represent allowable subject matter.

Malaviya in view of Schwartz

The Examiner rejects claims 20 and 34-37 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of US Patent No. 6,468,314 of Schwartz et al. ("Schwartz"). Applicants respectfully disagree.

At the outset, claims 20 and 34-37 ultimately depend from claim 1 and therefore distinguishes over Malaviya for all the reasons discussed above with respect to claim 1. Schwartz fails to remedy the deficiencies of Malaviya with respect to the claimed cell growth conduit flap including at least one channel configured to communicate biological materials to a tissue defect in the meniscus.

Moreover, claim 20 recites that the cell growth conduit flap has a void volume in the range of about 50 % to 95 %. One of ordinary skill in the art would not have modified the covers 232, 234 of Malaviya, which the Examiner argues form the claimed cell growth conduit flap, based on the void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. The insert thus bears no relation to the covers 232, 234 of Malaviya. Thus, even if it would have been obvious to modify Malaviya in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 20 and claims 34-37 distinguish over Malaviya in view of Schwartz and represents allowable subject matter.

Malaviya in view of Vallee and Schwartz

The Examiner rejects claims 39 and 41 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of Vallee and further in view of Schwartz. Applicants respectfully disagree.

Claims 39 and 41 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya in view of Vallee for all the reasons discussed above with respect to claims 21 and 25.

Moreover, claims 39 and 41 each recite that the cell growth conduit flap has a void volume in the range of about 50% to 95%. However, as discussed above with respect to claim 20, one of ordinary skill in the art would not have modified the covers of Malaviya based on the void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. Thus, even if it would have been obvious to modify Malaviya in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 39 and 41 distinguish over Malaviya '797 in view of Vallee and Schwartz and represent allowable subject matter.

New Claims 42, 43 and 44

As noted above, new claims 42, 43, and 44 are added, which recite that the at least one channel is on the surface of the cell growth conduit flap. These new claims depend from claims 1, 21, and 25, respectively and therefore distinguish over the cited art for at least the same reasons as discussed above for those claims. New claims also distinguish over the cited art for additional reasons.

None of the cited references teaches or suggests, among other things, a cell growth conduit flap comprising at least one channel on the surface of the cell growth conduit flap that is configured to communicate biological materials to a tissue defect in the meniscus. As discussed above, the Examiner "considers the pores in the material of Malaviya to be channels that communicate biological materials to the defect as discussed in paragraph 148." Office Action at page 2. However, even if there were any teaching or suggestion of pores in Malaviya's material that could communicate biological materials to a defect (which, as discussed above, there is not), any such pores would not be on the surface of Malaviya's implant and would not form a channel thereon. To the contrary, Malaviya discloses that the

outer surface of the implant is toughened, e.g., by heating, compression, and crosslinking. *See, e.g.*, Malaviya at paragraph 0057. Vallee, Li, and Schwartz fail to remedy the deficiencies of Malaviya.

Accordingly, new claims 42, 43, and 44 distinguish over the cited references and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

Dated: February 16, 2011

Respectfully submitted,

By / George A. Xixis/

George A. Xixis
Registration No.: 38,664
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617)439-2746
(617) 310-9746 (FAX)
Attorney for Applicants

1988808.1